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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/056,453 | 01/23/2002 | Fred Burbank | 9619-1191 | 5144 |

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02/14/2006

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|---------------------------------------|--|
| Office Action Summary | Application No. 10/056,453 | Applicant(s) BURBANK ET AL. | |
| | Examiner Jeffrey G. Hoekstra | Art Unit 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Information Disclosure Statement

2. The information disclosure statement(s) (IDS) submitted on 01/23/2002, 09/23/2002, and 06/02/2005 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).
3. It is noted the examiner considered neither the foreign patent documents nor the non-patent literature as it was filed in previous applications that have since been issued and thus the documents were unavailable.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 37-47, 49, 51, 53-56, and 64-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Kresch et al (5527331). For claims 37-38, Kresch et al discloses a

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disposable drive unit for engaging and holding a biopsy device, said biopsy device comprising a shaft P, an electrosurgical member 202 distally secured to said shaft, and a deployment mechanism 30 connected with a deployable element C, wherein said drive unit comprising a receptacle H, an electrical connector 204 connecting a RF power source to said biopsy device, and a mechanical connector 125 connecting a mechanical power source.

6. For claim 39, Kresch et al discloses a drive element 46 configured to engage a shuttle 48 that is operably connected to said deployment mechanism.

7. For claim 40, Kresch et al discloses an electrosurgical cutting element 202 as a deployment element.

8. For claims 41-42, Kresch et al discloses a drive gear 48 engaging said shaft and wherein said mechanical connector comprises a spindle 125, both of which are for transmitting rotary type mechanical power.

9. For claims 43-44, Kresch et al discloses a motor unit for engaging and providing power to a drive unit comprising a securing mechanism 45 forming a stable mechanical engagement between said motor and drive unit and a coupling mechanism 46 configured to engage said mechanical connector to transfer mechanical power.

10. For claim 45, Kresch et al discloses said coupling mechanism, transmitting rotary mechanical motion, comprising a ridged sleeve 47 adapted to receive a spindle.

11. For claim 46, Kresch et al discloses a targeted tissue removal biopsy system comprising a biopsy device having a wand, said wand comprising a shaft P, an electrosurgical member 202 distally secured to said shaft, an electrical connector 204

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connecting an electrical power source to said biopsy device, a deployable element C connected to said shaft, and a drive unit for engaging and holding a biopsy device having a wand, said drive unit comprising a receptacle H configured to engage and hold said biopsy device having a wand, an electrical connector 204 connecting a RF power source to said biopsy device, a mechanical connector 125 connecting and transferring mechanical power from a mechanical power source and a motor unit for engaging and providing power to a drive unit, said motor unit comprising a securing mechanism 45 forming a stable mechanical engagement between said motor and drive unit and a coupling mechanism 46 configured to engage said mechanical connector to transfer mechanical power.

12. For claims 47 and 49, Kresch et al discloses a deployable side-cutting mechanism configured to be axially translated about said shaft effective to isolate a body of target tissue when disposed within a patient (column 13 lines 54-59).

13. For claim 51, Kresch et al discloses a drive element 46 configured to engage a shuttle 48 that is operably connected to said deployment mechanism for deployment or retraction.

14. For claims 53-54, Kresch et al discloses a drive gear 48 engaging said shaft and wherein said mechanical connector comprises a spindle 125, both of which are for transmitting rotary type mechanical power.

15. For claims 55-56, Kresch et al discloses a motor unit for engaging and providing power to a drive unit comprising a snap-in securing mechanism 45 forming a stable mechanical engagement between said motor and drive unit and coupling mechanism,

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transmitting rotary mechanical motion, comprising a ridged sleeve 47 adapted to receive a spindle.

16. For claims 64-65, Kresch et al discloses a handle H configured for engaging and holding a biopsy device, said biopsy device comprising a shaft P, an electrosurgical member 202 distally secured to said shaft, and a deployment mechanism 30 connected with a deployable element C, wherein said drive unit comprising a receptacle H, an electrical connector 204 connecting a RF power source to said biopsy device, and a mechanical plunger element 50 configured for connecting a mechanical power source to said deployable fixation mechanism and aiding in deployment.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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19. Claims 48, 50, 52, 57, and 59-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kresch et al in view of Gough et al (5683384).

20. For claims 48, 50, and 52, Kresch et al discloses the claimed invention except for the anchoring mechanism. Gough et al teaches a radial wire radial wire anchoring mechanism located proximal to the distal end of said shaft, as best seen in Figures 6-8. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the biopsy device as taught by Kresch et al, with Gough et al for the purpose of stabilizing a biopsy device in a targeted tissue site for enhanced targeted tissue removal.

21. For claim 57, Kresch et al discloses the claimed invention except for the anchoring mechanism coupled to an elongated electrode wherein said wand further comprises a second electrical connector for connecting said electrode and electrical power source. Gough et al teaches elongated electrodes 24 distally disposed along said anchoring mechanism and in electrical connecting 22 with an electrical power source. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the biopsy device as taught by Kresch et al, with Gough et al for the purpose of powering distal electrodes to function within targeted tissue sites for enhanced tissue removal.

22. Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kresch et al in view of Desai (5395312). Kresch et al discloses the claimed invention except for the electrosurgical cutting member extending beyond the distal end of the shaft. Desai teaches a targeted tissue surgical instrument with an electrosurgical cutting member

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266 extending beyond the distal end of the shaft 264. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the biopsy device as taught by Kresch et al, with Desai for the purpose of enhanced targeted tissue removal via a tissue removal device configured to removal tissue distal the distal tip.

23. For claims 59-62, Kresch et al discloses the claimed invention except for the anchoring mechanism formed of electrically conducting metallic wires or ribbons in electrical contact with a proximal electrical power source and comprising a plurality of outwardly extending members configured to penetrate tissue. Gough et al teaches a plurality of conductive wire elongated tissue penetrating antennas 16 (column 6 lines 5-10) in electrical contact with a proximal power source (Figure 10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the biopsy device as taught by Kresch et al, with Gough et al for the purpose of securing tissue ablation antennae into targeted tissue for ablation.

24. For claim 63, Kresch et al discloses the claimed invention except for the anchoring mechanism mounted movably along said shaft such that radial contraction facilitates advancement of the device and radial expansion facilitates targeted tissue penetration. Gough et al teaches a plurality of tissue penetrating antennas 16 movably mounted along said shaft that contract and expand. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the biopsy device as taught by Kresch et al, with Gough et al for the purpose aiding in targeted tissue ablation.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JGH

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MAX F. HINDENBURG

SENIOR PATENT EXAMINER

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